

# Overview of new Biocidal Product Regulation - Impacts on biocides & biocide-treated articles imported into the EU

The Latest Trends in the EU  
Chemicals Management: REACH, CLP & BPR

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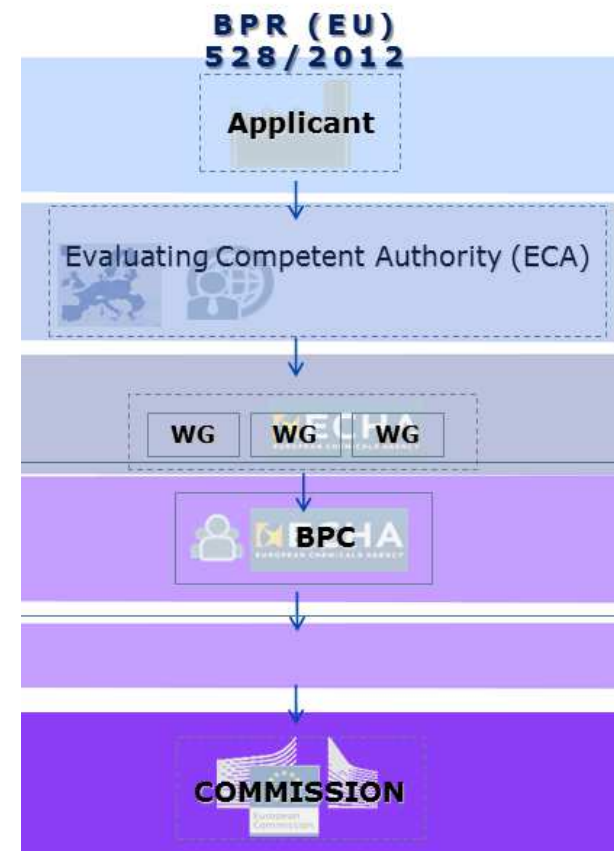
## New Regulation

- **Biocidal Product Regulation (EU) 528/2012**
  - Replaces the Biocidal products Directive (98/8/EC)
- Adopted in May 2012
- Entered in the **operation 1 September 2013**
- Link to the text via ECHA website  
<http://echa.europa.eu/regulations/biocidal-products-regulation>
- Covers biocidal products not regulated by:
  - pesticides, veterinary medicines, cosmetics legislation



# Why from Directive to Regulation?

- Improve the functioning of the EU market for biocides
- Ensure high level of protection of human health and the environment
- Simplifies and streamlines processes
- Reduces animal testing
  - Compulsory data/cost sharing
  - Encourages more flexible and intelligent approach to testing



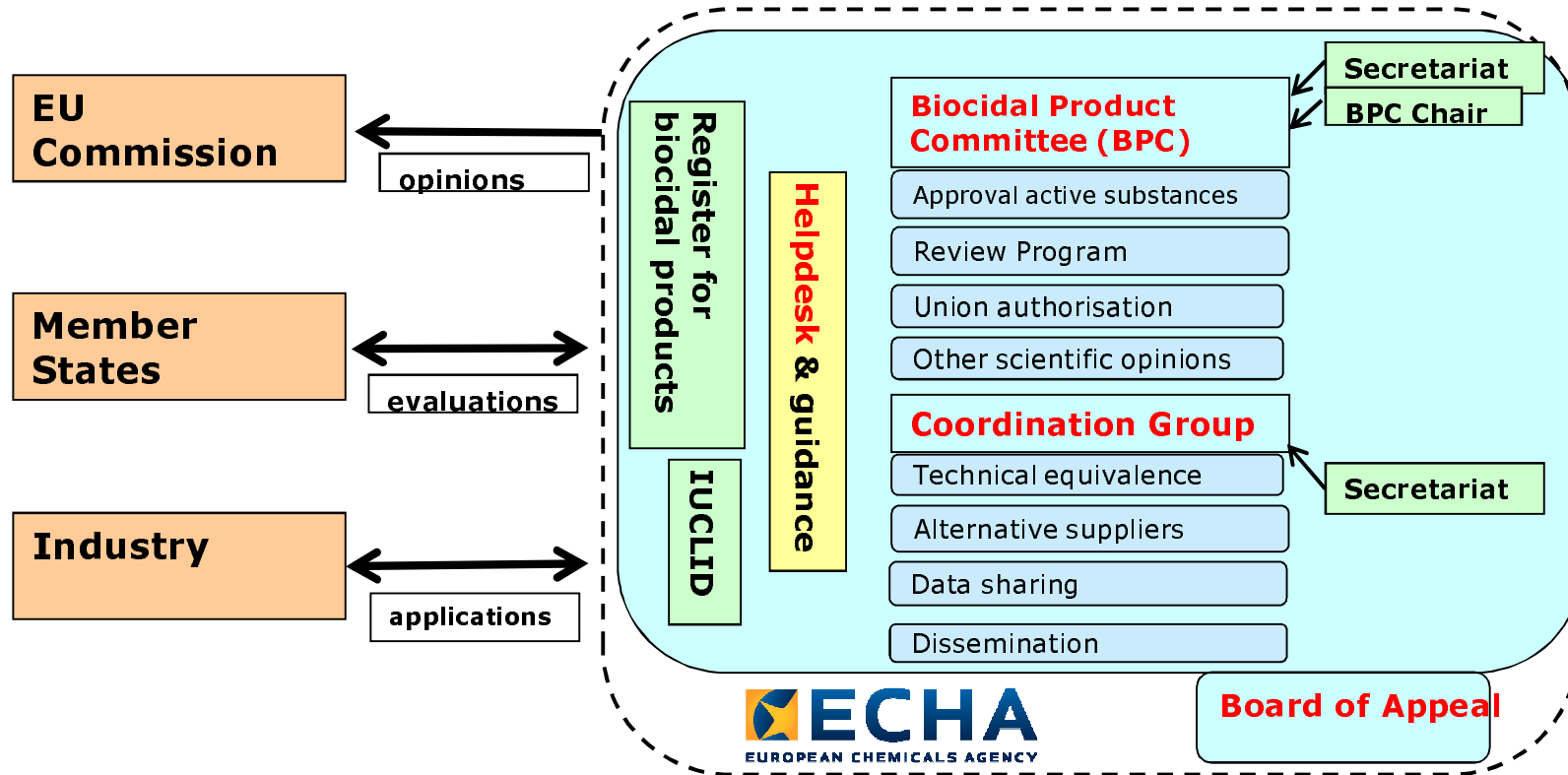
# Regulation vs. Directive

- New definitions cover:
  - *in situ* generation
  - placing on the market
  - nanomaterials
- Requirements for **treated articles**
- Hazard based exclusion & substitution
- Detailed procedure for **mutual recognition**
- **Union authorisation** of biocidal products possible
- Harmonised “summary of the product characteristics” for authorisation

Directive	Regulation
98/8/EC	EU 528/2012
Annex I-inclusion	Approval
Annex I	List of approved substances
Annex IA	Annex I
Low-risk products	Products eligible for the simplified procedure
Frame formulation	Biocidal product family

# ECHA & BPR

- **Coordination** of procedures & **centralisation** of tasks that are better dealt at EU level rather than at each Member State



## Basic Concepts

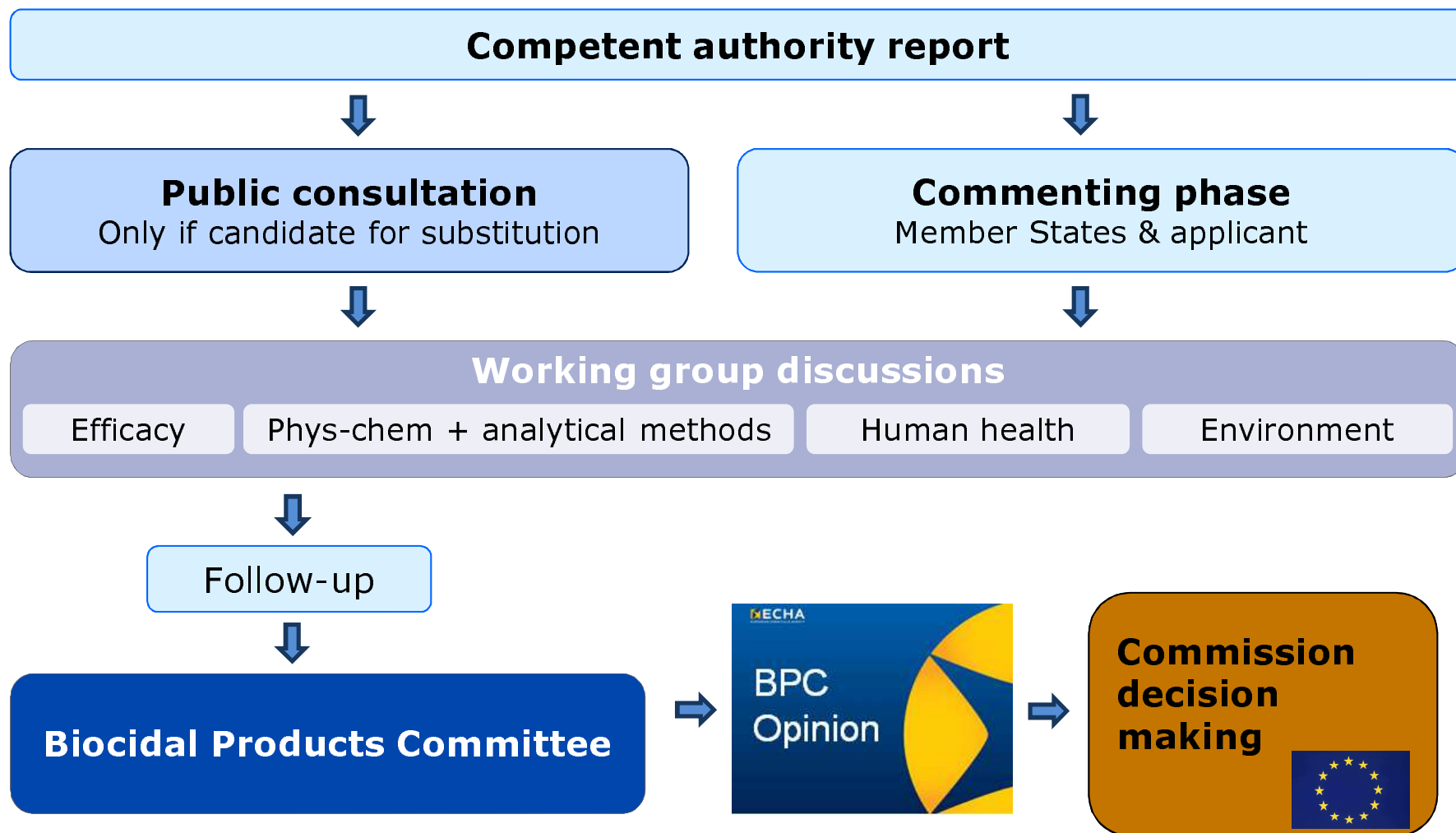
- **Active substance:** a substance or a micro-organism that has an action on or against harmful organisms
  - Harmful organism: an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment
- **Biocidal products:**
  - Split into 22 Product Types (Annex V)

# Main groups and product types

- **Disinfectants**
  - human hygiene (1), public health (2), veterinary (3), food and feed areas (4), drinking water (5)
- **Preservatives**
  - in-can (6), film (7), wood (8), fibre (9), construction material (10), liquid cooling (11), slimicides (12), metal working fluids (13)
- **Pest control**
  - rodenticides (14), avicides (15), molluscicides (16), piscicides (17), insecticides (18), repellents (19), other invertebrates (20)
- **Other**
  - antifouling products (21), embalming/taxidermist fluids (22)



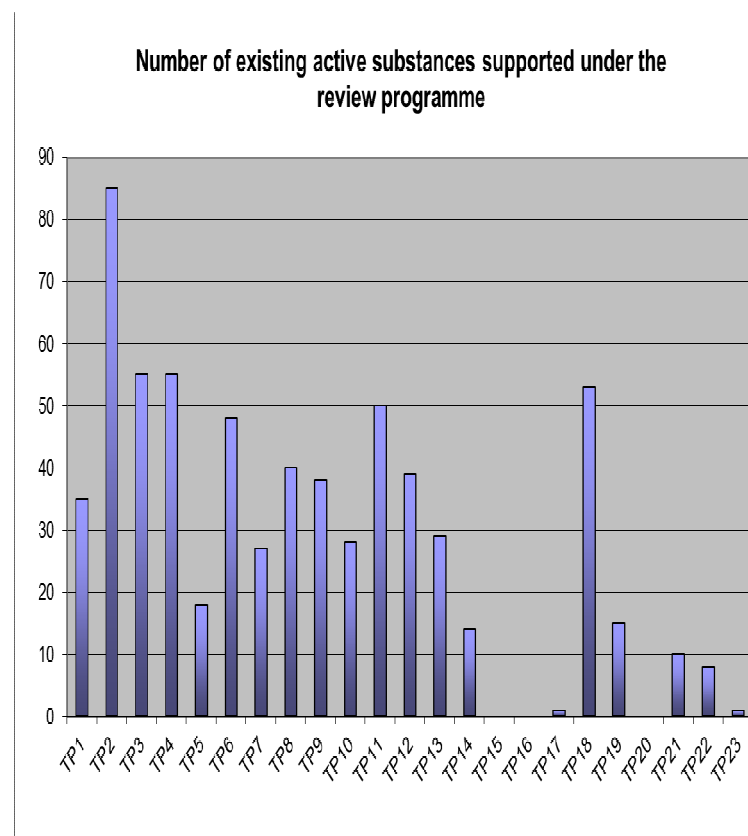
# Review of Actives – main steps





# Review Programme

- Number of **Active Substance - Product-Type** dossiers:
  - *Total: 660*
  - *Approved: 70*
  - *In peer review process at EU level: 160*
  - *Still to be submitted by Member States: 430*
- Commission intends to decide on 30 dossiers in the second half of 2013
- Extended from 14 May 2014 to 31 December 2024



## Active Substance Approval

### **Faster process** for all new applications:

- One year evaluation stage
- 270 days for opinion forming
- Possibility of stopping the clock during evaluation
  - Up to 180 days; more if justified by the nature of the data requested or by exceptional circumstances
- **Overall:** around two years from submission of application to BPC opinion
  - Followed by COM implementing act

## Active Substances Exclusion of “SVHC”

- Substances that:
  - are **CMR** (Carcinogens, Mutagens, or toxic for Reproduction category) **1A** or **1B**, or
  - are **PBT** (Persistent, Bioaccumulative and Toxic), or **vPvB** (very Persistent and very Bioaccumulative), or
  - have **ED** (endocrine-disrupting) properties
- “SVHC” **cannot be approved** as Active Substances **unless**:
  - Exposure is negligible, or
  - The substance is essential to control a serious danger to human or animal health or to the environment, or
  - Non-approval will have disproportionate negative impact for society

## Active Substances substitution

- If an active substance is a **candidate for substitution**
  - Biocidal product is subject to comparative assessment
  - 60-day **public consultation** by ECHA:
    - Third parties to provide relevant information
    - Mainly information on available substitutes expected
- **Explicit evaluation** of the criteria in Competent Authority Report
  - Only the final outcome of assessment will confirm whether criteria are met

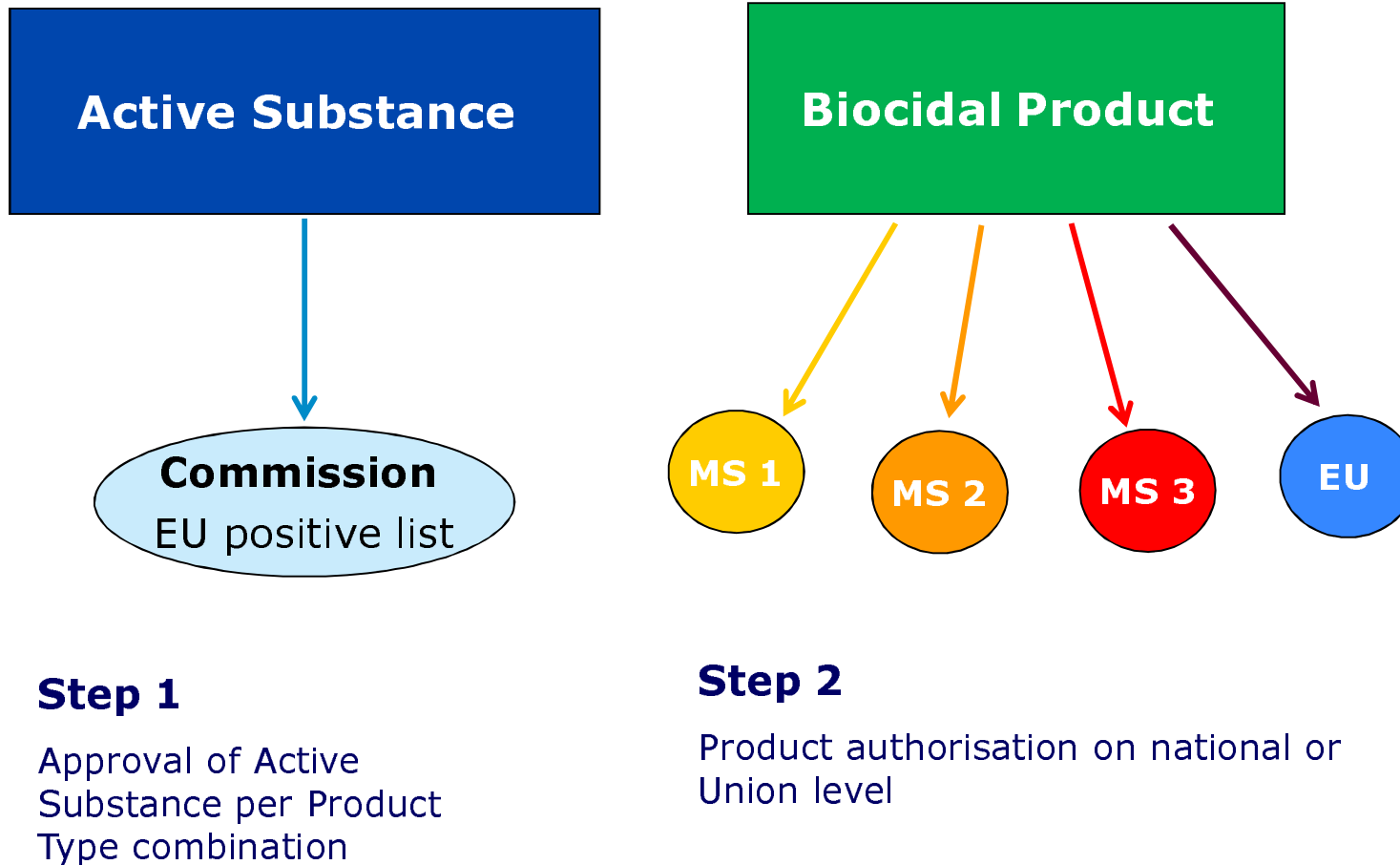
# Data sharing is mandatory

- Submitted to ECHA **via R4BP**
- **Minimise testing** on animals & monopolistic situations of suppliers of Active Substances
- Applies to:
  - Data from tests on **vertebrate animals** on all tox- and eco-tox studies for existing active substances
  - with regards to alternative suppliers
- Prospective applicant & data owner must **seek agreement**
- **Compensation** for data is determined in a fair, transparent and non-discriminatory manner, share the cost of information to be submitted for this regulation
- If negotiation fails, ECHA gives prospective applicant **right to refer**, and proportionate share of the cost to be paid fixed by national courts

# Active Substances Cost Sharing

- All active substance manufacturers or importers must submit a dossier or a letter of access to ECHA as of **1 Sep 2013**
- ECHA will establish a list of manufacturers or importers who complied with this obligation
- **From 1 Sep 2015:** only biocidal products with a listed source of Active Substance can be made available on the market
- Data protection for existing substances in the review programme expires **31 Dec 2025** at the latest

# Biocidal Products – a 2-step approach



## Union Authorisation

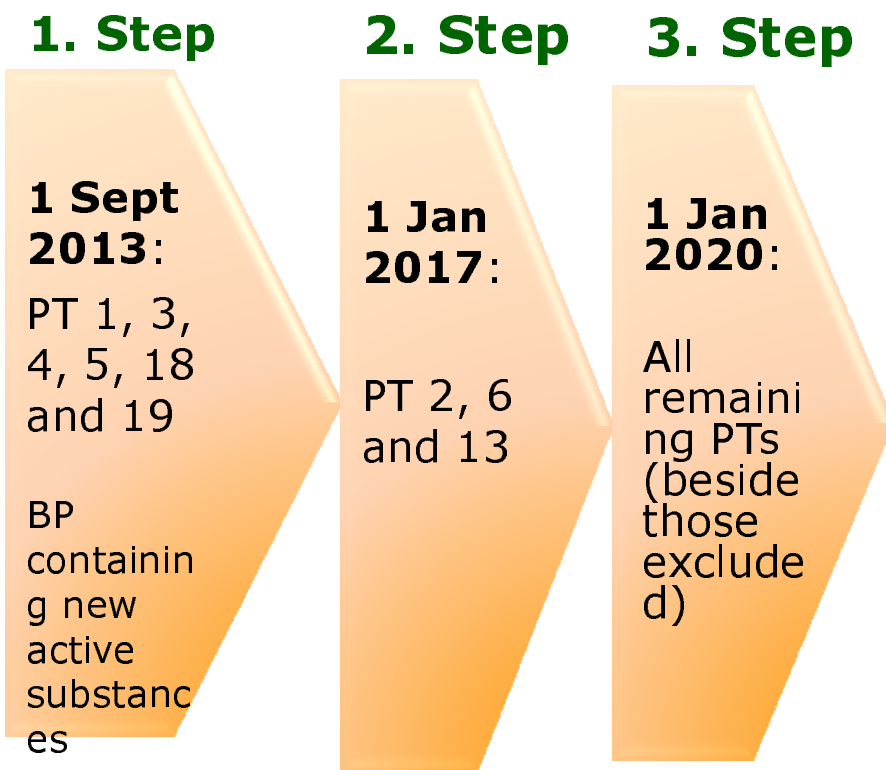
- Authorisation given by the EU Commission, valid on the entire Union market
- For **single** biocidal **products or** product **families** with similar conditions of use across EU
- Excluded:
  - Products containing substances fulfilling the exclusion criteria
  - Products to control rodents, birds, fish, and other vertebrates (PTs 14, 15, 17 and 20)
  - Antifouling products (PT 21)



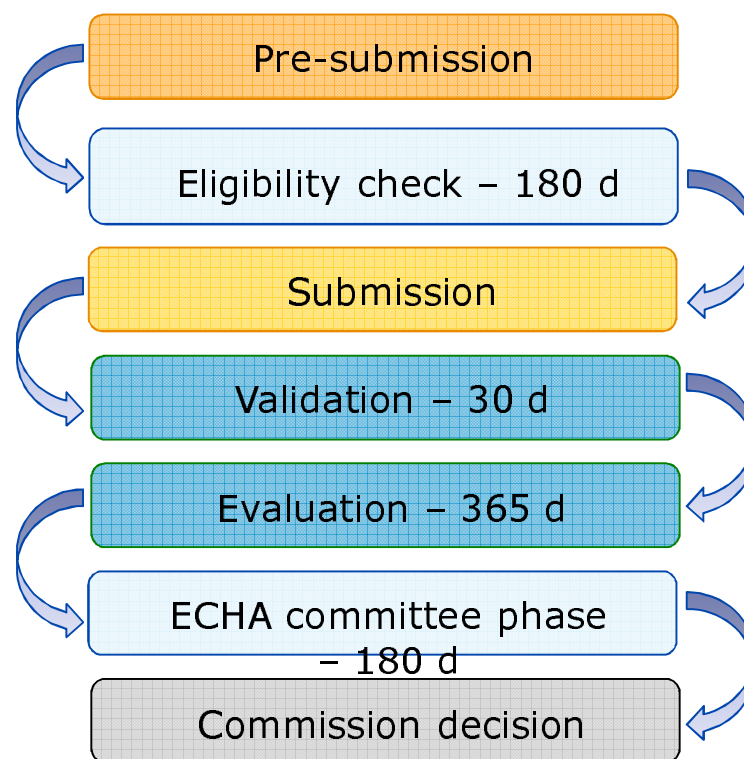


# Union Authorisation

## Transition



## Timeline



## Predicted number of BPC opinions (DG-ENV February 2013)

	Legal Time limit (days)	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Approval of new active substances	270	0	0	2	5	5	5	5	5	5	5
Approval of existing active substances (RP)	270	0	50	50	50	50	50	50	50	50	50
Renewal of active substance approvals	270 (full) 90 (partial)	0	2	3	3	0	0	1	8	12	12
<b>Union authorisation of biocidal products</b>	180	0	<b>5</b>	<b>12</b>	<b>23</b>	<b>77</b>	<b>79</b>	<b>76</b>	<b>131</b>	<b>143</b>	<b>162</b>
Amendments of Union authorisations	90	0	0	0	0	1	2	4	12	20	27
Disagreement mutual recognition	120	0	30	30	30	30	30	30	30	30	30
<b>Total</b>		<b>0</b>	<b>87</b>	<b>97</b>	<b>111</b>	<b>162</b>	<b>167</b>	<b>166</b>	<b>236</b>	<b>259</b>	<b>286</b>

## Union Authorisation Advantages

- Facilitates the making available of biocidal products with similar conditions of use on the EU market
  - **Simplifies procedures** for economic operators targeting several Member State markets
  - **Reduces** the overall **administrative burden**
  - **Single authorisation** for the entire Union market will have a positive impact on product availability.
  - **Fixed deadlines** will provide more certainty for applicants.
  - **Harmonised procedures** will improve consistency in the dossiers' assessment.

## Biocidal Products Mutual Recognition

- Clear procedures including mechanisms to deal with objections and derogations, for better enforcement
- Options:
  - **in sequence:** application when product is already authorised in one Member State, or
  - **in parallel:** application when product is not yet authorised
- **90 days** for Member States to coordinate & agree
- If no agreement, then Commission decides
  - **Disagreements** referred to the Commission, possibly based on ECHA opinion

## Biocidal Products Simplified Procedure

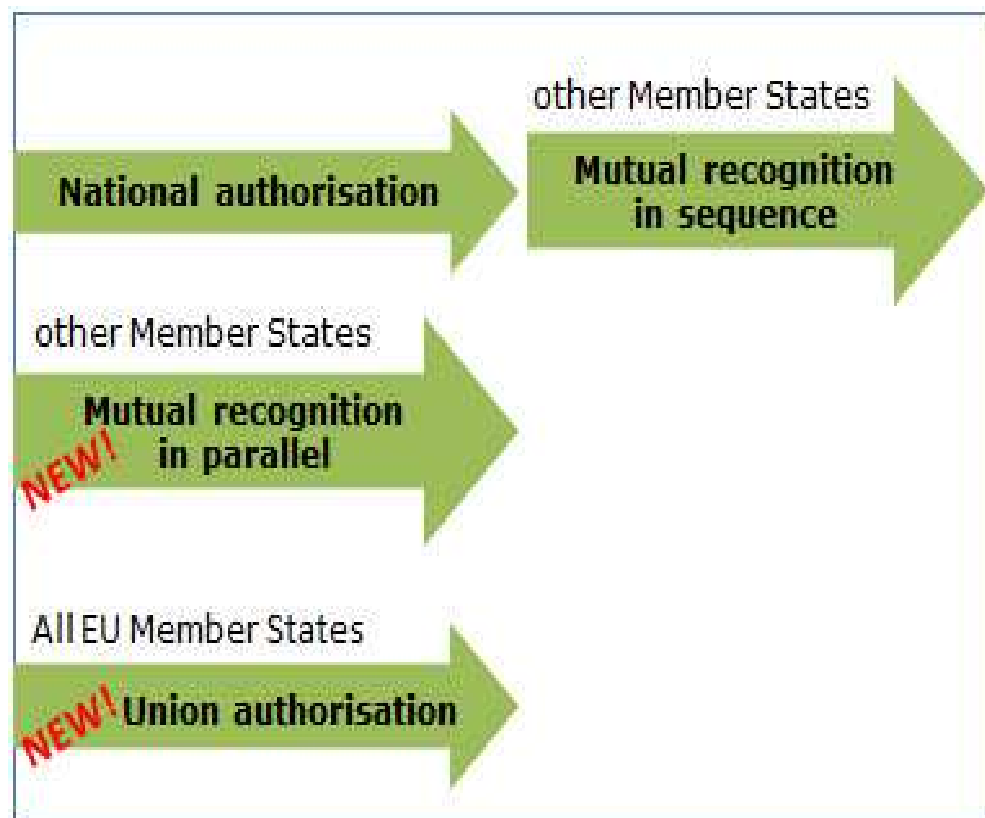
- Facilitates the marketing of product with **lower concern/better profiles** with regard to health & environment:
  - All Active Substances listed in **Annex I**
  - Contain **no substance of concern** or **no nanomaterials**
  - Sufficient **efficacy**
  - **No** need to wear **PPE** (Personal Protective Equipment)
- **Benefits** for product authorisation
  - Faster procedure: Member State evaluation in 90 days
  - Once given by one Member State, the product can be made available on the whole EU market, after a Notification to ECHA

# Comparative assessment of Products

- **During** the assessment of the authorisation of:
  - Biocidal Product or
  - Renewal of authorisation (either at Member State or EU level)
- Products containing candidates for substitution will not be authorised if **alternatives**:
  - Present significantly lower risk
  - Are sufficiently effective, and
  - Present no significant economic or practical disadvantage, and
  - Chemical diversity adequate to minimise resistance

# Product Authorisation Summary

Authorisation of Biocidal Products for a maximum of 10 years



## Treated articles

- **Definition**
  - *Substance, mixture or article*
  - *Treated with or intentionally incorporating **biocidal products***
- **Active substance** in biocidal product with which the article is treated needs to be approved in the EU
- Technical **guidance** is being developed





## Treated articles

- Conditions for **placing on the market**
  - Article has to **comply with** all relevant **conditions of approval** of the active substance
- **Substance/product-type combinations** that have not yet been approved are allowed if
  - Combination is still **in the review programme**, or
  - **An application** for approval is **submitted** before 1 September 2016

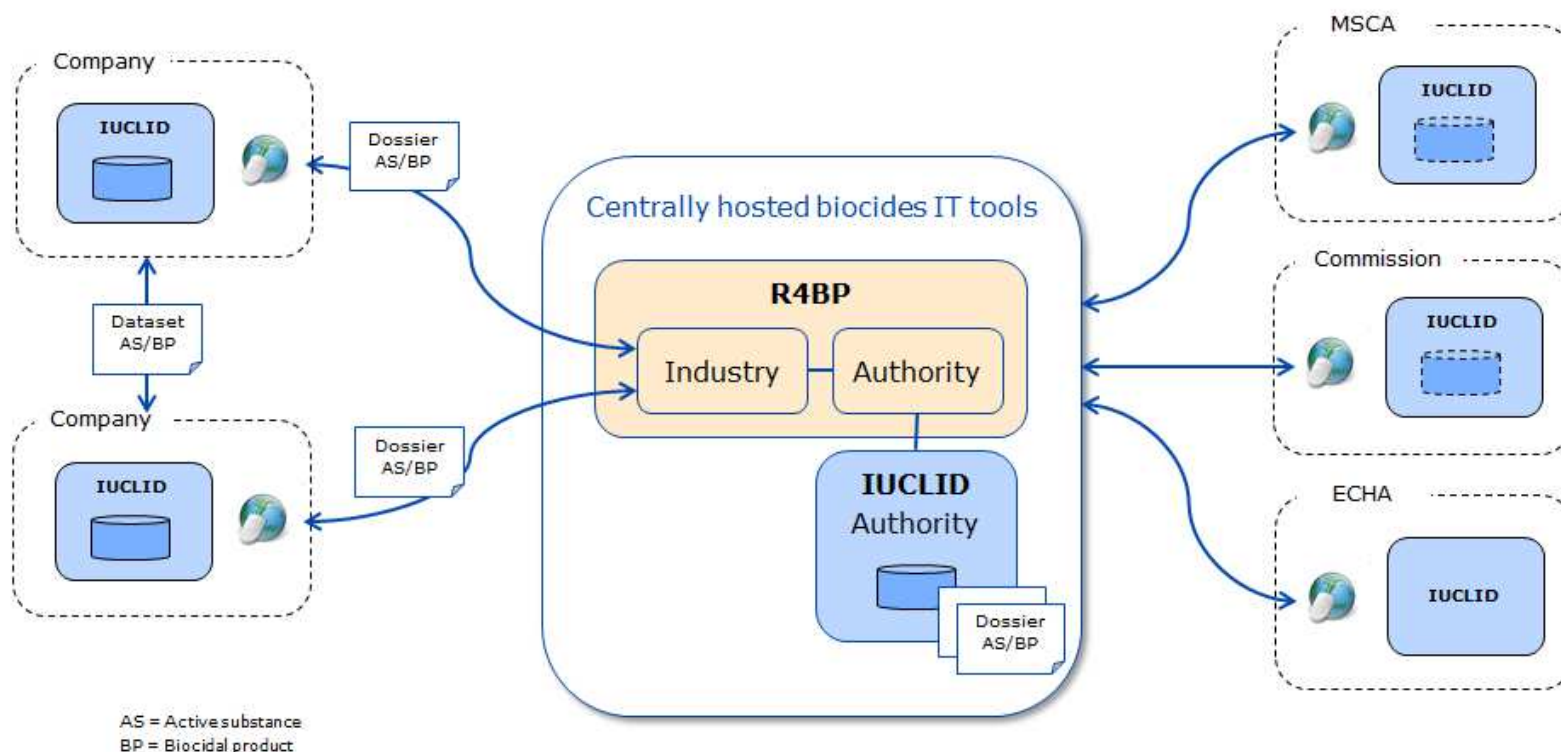


## Treated articles - labelling

- **Required if**
  - **Claim is made** regarding biocidal properties of the article, or
  - **Conditions of substance approval so require**
- Information to be provided in the **national language**
  - *Statement that article incorporates a biocide*
  - *Biocidal property of the article*
  - *Name of all active substances & nanomaterials*
  - *Instructions for use where necessary to protect man or environment*



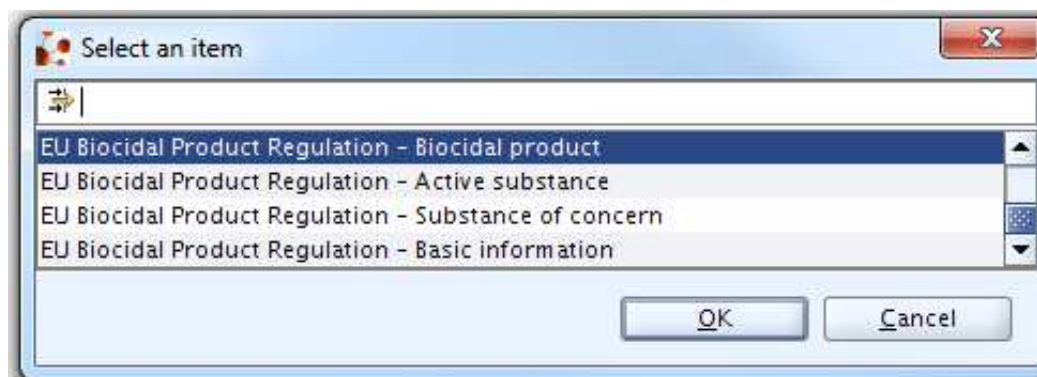
# IT tools for BPR



## R4BP3 and IUCLID 5.5: common hub and paperless system

## IUCLID 5.5 – key features for biocides

- Released on 2 April
  - 9 new data templates for BPR-specific information
  - New dossier types
  - View for active substances & biocidal products in line with numbering of the BPR info requirements annexes
- Biocidal product composition
  - Technical characteristics of the biocidal product
  - Phys-chem compatibility with other products including other biocidal products with which its use is to be authorised
  - Product types and uses
  - Biocidal use tonnage
  - Toxicological profile for humans and animals including metabolism
  - Measures to protect humans, animals and the environment
  - Packaging
  - Summary & evaluation



## Biocidal Products Regulation

The Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product.

> [Understanding BPR](#)

> [Legislation](#)

### Processes



Companies can apply for the approval of an active substance by submitting a dossier to ECHA.

> [Approval of active substances](#)



After the approval of an active substance, companies wishing to place biocidal products on the market have to apply for product authorisation at national or Union level.

> [Authorisation of biocidal products](#)



Companies can ask ECHA to establish the technical equivalence of their active substance.

> [Technical equivalence](#)



Manufacturers and importers not involved with the review programme of the previous legislation have to submit certain information to ECHA.

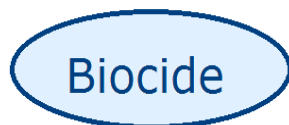
> [Alternative suppliers](#)

<http://echa.europa.eu/regulations/biocidal-products-regulation>

## ECHA Helpdesk advice on BPR



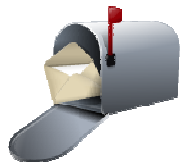
**Customer:** Applicants, particularly SMEs



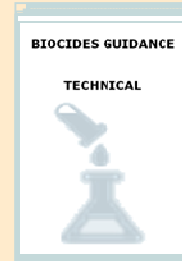
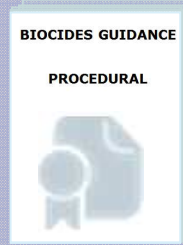
**Topics:** Approval of Active Substance, inclusion in Annex I, Union authorisation



**Scope:** Advice and assistance



**Communication:** Helpdesk contact form, written replies



**Expertise areas**

**ACTIVE SUBSTANCES RELATED**

**BIOCIDAL PRODUCTS RELATED**

**IDENTITY, PHYS-CHEM, ANALYTIC  
VOLUME I**

**EFFICACY RESISTANCE UN-EFFECTS  
VOLUME II**

**HUMAN HEALTH  
VOLUME III**

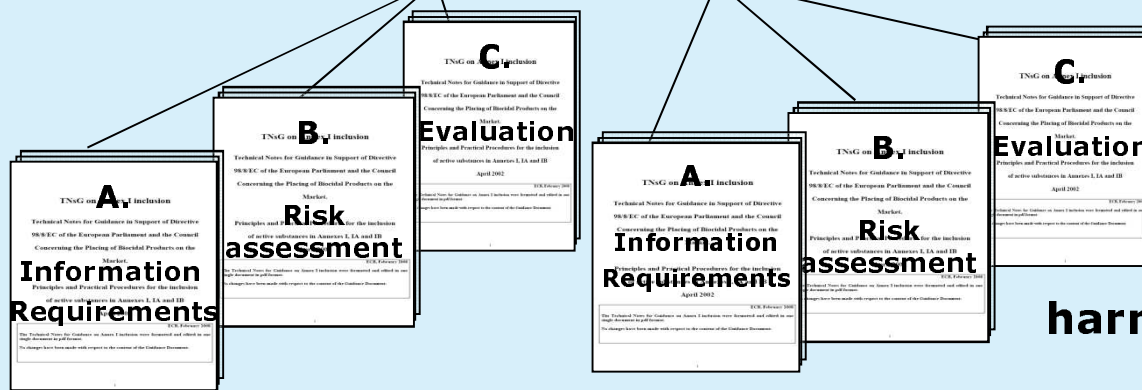
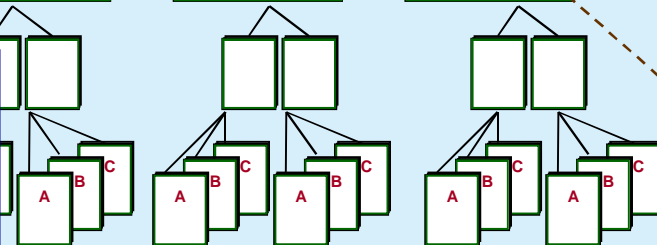
**ENVIRONMENT  
VOLUME IV**

**New guidance package**



CHAPTER I OF TITLE I - ACTION  
1.1 GENERAL OBJECTIVES  
1.1.1 Background  
1.1.2 When the guidance is for  
1.1.3 Why the guidance is needed

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**Self-explaining structure**

**Concise and harmonised information**

**Guidance**

**Up-to-date**

## Publishing schedule 2013 & beyond

- Guidance on information requirements Part A (July 2013)
- Guidance on technical equivalence (1 Sep 2013)
- Guidance on alternative suppliers (1 Sep 2013)
- Guidance on procedural aspects in relation to active substances (by Q1 2014)
- Guidance on procedural aspects in relation to biocidal products (by Q1 2014)
- Guidance on mixture toxicity
- Guidance on risk assessment – Human Health – part B
- Guidance on risk assessment – Environment– part B
- Guidance on micro-organisms
- Guidance on efficacy assessment- part B
- Guidance on phys-chem/analytics assessment- part B
- Guidance on evaluation – part C of all 4 volumes
- Guidance on various specific topics transferred from the BPD framework as becomes available and depending on its importance (unless integrated in the overall BPR structure)



## Worth to Remember about Biocides Regulation

- Streamlines the processes & enhances the decision making
- Opportunities for businesses, but companies need to learn and understand their duties and timelines
- ECHA provides companies with support, IT tools & guidance
- Pay attention to the requirements for treated articles & alternative suppliers

**Thank you !**